EXHIBIT “A”

IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA

JENNIFER GILLESPIE and BRIAN GILLESPIE, wife and husband,

Plaintiffs,

vs.

SOFREGEN MEDICAL, INC.; ALLERGAN, INC.; and ABBVIE, INC., successor-in-interest to ALLERGAN, INC.,

Defendants.

CIVIL DIVISION

CASE NO.: GD 21-001852

JURY TRIAL DEMANDED

TYPE OF PLEADING:
COMPLAINT IN CIVIL ACTION

FILED ON BEHALF OF:
PLAINTIFFS, JENNIFER GILLESPIE and BRIAN GILLESPIE

TO: DEFENDANTS

You are hereby notified to file a written response to the within Complaint in Civil Action within Twenty (20) days of service hereof or judgment may be entered against you.

McKENNA & ASSOCIATES, P.C.

BY: _____
MARK F. McKENNA, ESQUIRE
Attorneys for Plaintiffs

COUNSEL OF RECORD FOR THIS PARTY:

MARK F. McKENNA, ESQUIRE
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IN THE COURT OF COMMON PLEAS OF ALLEGHENY COUNTY, PENNSYLVANIA

JENNIFER GILLESPIE and BRIAN GILLESPIE, wife and husband, Plaintiffs, vs. SOFREGEN MEDICAL, INC.; ALLERGAN, INC.; and ABBVIE, INC., successor-in-interest to ALLERGAN, INC., Defendants.	)	CIVIL DIVISION CASE NO: GD 21-001852 **JURY TRIAL DEMANDED**

NOTICE TO DEFEND

YOU HAVE BEEN SUED IN COURT. If you wish to defend against the claims set forth in the following pages, you must take action within TWENTY (20) DAYS after this Complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the Court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so, the case may proceed without you, and a judgment may be entered against you by the Court without further notice for any money claimed in the Complaint or for any claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, [OR CANNOT AFFORD ONE] GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW [TO FIND OUT WHERE YOU CAN GET LEGAL HELP]. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

LAWYER REFERRAL SERVICE
Allegheny County Bar Association
400 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219
Telephone: (412) 261-5555
https://www.getapittsburghlawyer.com/

COMPLAINT IN CIVIL ACTION

AND NOW, come Plaintiffs, Jennifer Gillespie and Brian Gillespie, by and through their attorneys, McKENNA & ASSOCIATES, P.C., and file the following Complaint in Civil Action against the Defendants, Sofregen Medical, Inc., Allergan, Inc., and Abbvie, Inc., successor-in-interest to Allergan, Inc., upon causes of action of which the following is a statement:

1. Plaintiff, Jennifer Gillespie, is an adult individual who resides at 1271 Redfern Drive, Pittsburgh, Allegheny County, Pennsylvania 15241.

2. Plaintiff, Brian Gillespie, is an adult individual who, at all times relevant hereto was the spouse of Plaintiff Jennifer Gillespie and who resided with her at 1271 Redfern Drive, Pittsburgh, Allegheny County, Pennsylvania 15241. (Plaintiff Jennifer Gillespie is sometimes hereinafter referred to as "Plaintiff-Wife", Plaintiff Brian Gillespie is sometimes hereinafter referred to as "Plaintiff-Husband" and Plaintiffs Jennifer Gillespie and Brian Gillespie are sometimes referred to collectively as "Plaintiffs").

3. Defendant, Sofregen Medical, Inc. (hereinafter referred to as "Defendant Sofregen"), is a Delaware corporation with a principal place of business located at 175 Crossing Boulevard, Framington, Massachusetts 07102.

4. Defendant Sofregen is currently and has at all times relevant hereto been engaged in the practice of designing, manufacturing, testing, marketing, assembling, inspecting, selling, supplying, distributing for sale and use, and/or making available for sale, distribution and use silk-derived biological scaffold including but not limited to the Seri Surgical Scaffold.

5. Defendant Sofregen regularly conducts business in the Commonwealth of Pennsylvania, including Allegheny County, Pennsylvania.

6. At all times relevant to the matters complained of within this Complaint, Defendant Sofregen was acting through its agents, ostensible agents, servants and/or employees, namely its engineers, designers, physicians, physicians' assistants, nurses, nurses' assistants, researchers and/or technicians, each of whom was acting within the course of their respective employment and within the scope of their respective authority.

7. Defendant, Allergan, Inc. (hereinafter referred to as "Defendant Allergan"), is a Delaware corporation with a principal place of business located at 2525 Dupont Drive, Irvine, California, 92612.

8. Defendant Allergan is currently and has at all times relevant hereto been engaged in the practice of designing, manufacturing, testing, marketing, assembling, inspecting, selling, supplying, distributing for sale and use, and/or making available for sale, distribution and use silk-derived biological scaffold including but not limited to the Seri Surgical Scaffold.

9. Defendant Allergan regularly conducts business in the Commonwealth of Pennsylvania, including Allegheny County, Pennsylvania.

10. At all times relevant to the matters complained of within this Complaint, Defendant Allergan was acting through its agents, ostensible agents, servants and/or employees, namely its engineers, designers, physicians, physicians' assistants, nurses, nurses' assistants, researchers and/or technicians, each of whom was acting within the course of their respective employment and within the scope of their respective authority.

11. Defendant, Abbvie, Inc. (hereinafter referred to as "Defendant Abbvie"), is a Delaware corporation with a principal place of business located 1 N. Waukegan Road, North Chicago, Illinois 60045.

12. Defendant Abbvie is a successor-in-interest to Defendant Allergan.

13. Defendant Abbvie regularly conducts business in the Commonwealth of Pennsylvania, including Allegheny County, Pennsylvania.

14. Defendant Abbvie is currently and has at all times relevant hereto been engaged in the practice of designing, manufacturing, testing, marketing, assembling, inspecting, selling, supplying, distributing for sale and use, and/or making available for sale, distribution and use silk-derived biological scaffold including but not limited to the Seri Surgical Scaffold.

15. At all times relevant to the matters complained of within this Complaint, Defendant Abbvie was acting through its agents, ostensible agents, servants and/or employees, namely its engineers, designers, physicians, physicians' assistants, nurses, nurses' assistants, researchers and/or technicians, each of whom was acting within the course of their respective employment and within the scope of their respective authority.

16. Alternatively, Defendant Abbvie acquired/assumed the liability of Defendant Allergan, including all liability asserted with the Seri Surgical Scaffold of line of silk-derived biological scaffold.

FACTUAL BACKGROUND

17. Defendant Sofregen, Defendant Allergan and Defendant Abbvie (hereinafter collectively referred to as the "Defendants") individually and/or jointly participated in the design, manufacture, assembly, inspection, testing, approval, marketing, selling, supplying, distribution for sale and/or offering for sale and/or distribution of the Seri Surgical Scaffold.

18. On May 19, 2015, Plaintiff-Wife underwent a bilateral implant revision with Seri Surgical Scaffold, internal bra support and implant exchange, which procedure was performed by

Simona Pautler, M.D. at St. Clair Hospital due to complications from Plaintiff-Wife's April 16, 2012 bilateral breast augmentation with bilateral mastopexies surgery.

19. During the procedure, the internal support of implants was performed using 10 cm. x 25 cm. Seri Surgical Scaffold as an internal bra support.

20. It is believed and there averred that Draft Seri Surgical Scaffold Lot# P 13091601A was used.

21. In August 2015, approximately four (4) months after her surgery, Plaintiff-Wife started experiencing sharp burning pain and discomfort under her left breast.

22. Plaintiff-Wife also developed swollen lymph nodes in her right side, acne on her neck and face, hives, pain in ribs and clavicle, and occasion low grade fevers.

23. On May 29, 2015, the FDA issued a warning letter to Defendant Allergen that the Seri Surgical Scaffold was being promoted for unintended use as the device was not cleared or approved for use in breast reconstruction using a tissue expander or implant. (A copy of May 29, 2015 Warning Letter is attached hereto as Exhibit A.)

24. Plaintiff-Wife was not contacted by Defendants or others so advised of the May 29, 2015 action by the FDA by any source, including her surgeon.

25. Approximately four (4) years after her surgery, and due to ongoing complaints of pain, discomfort and pulling sensation in Plaintiff-Wife chest area, ribs and clavicle, Dr. Pautler advised Plaintiff-Wife of a recall on the Seri Surgical Scaffold.

26. On May 13, 2020, Plaintiff-Wife saw Kevin Cross, M.D., who recommended immediate removal of Seri Surgical Scaffold and implants.

27. On May 26, 2020, Plaintiff-Wife underwent breast pathology testing which

revealed fibro-membranous tissue with reactive changes and underlying skeletal muscle consistent with capsule, nodular proliferation of nerve fiber bundles consistent with traumatic neuroma.

28. On May 26, 2020, Plaintiff-Wife underwent bilateral implant removal with bilateral breast lift and fat grafting to the breasts, which procedure was performed by Dr. Cross.

29. In January 2021, Plaintiff-Wife has been diagnosed with Smoldering Myeloma.

COUNT I
STRICT LIABILITY
PLAINTIFFS v. SOFREGEN MEDICAL, INC.

30. Plaintiffs incorporate by reference hereto the allegations set forth with paragraphs 1 through 29, inclusive, as though the same were set forth more fully herein at length.

31. At all times relevant hereto, Defendant Sofregen designed, developed, tested, assembled, manufactured, packaged, labeled, prepared for distribution, distributed, marketed, supplied and/or sold the Seri Surgical Scaffold either directly and/or indirectly to healthcare providers, hospitals, physicians and medical care recipients, including Plaintiff-Wife.

32. Defendant Sofregen, directly and through its officers, directors and its agents, ostensible agents, servants and/or employees, including Defendant Allergan and Defendant Abbvie, who were acting within the scope of their authority, servitude, workmanship and/or employment described herein, is strictly liable and/or vicariously liable in some or all of the following particulars:

a. The Seri Surgical Scaffold was defective in its design;

b. The Seri Surgical Scaffold was defective in its construction and manufacture;

c. The Seri Surgical Scaffold was not designed or constructed with the proper material or in the proper manner for breast surgery application;

d. The Seri Surgical Scaffold was not accompanied by adequate warnings and instructions in regard to its application in breast reconstruction procedures;

e. In failing to provide healthcare providers, including St. Clair Hospital and Simona Pautler, M.D. with adequate instruction, direction and/or warning regarding the use of the Seri Surgical Scaffold in Plaintiff-Wife's bilateral breast augmentation with bilateral mastopexies surgery;

f. In failing to warn and/or adequately warn physicians and Plaintiff-Wife of any and all dangers and risks involved with the use of the Seri Surgical Scaffold; and

g. In failing to warn and/or adequately warn physicians and Plaintiff-Wife that use of the Seri Surgical Scaffold in breast reconstruction was an unintended and unapproved use of this device.

33. Defendant Sofregen, directly and through its officers, directors and its agents, ostensible agents, servants and/or employees, including Defendant Allergan and Defendant Abbvie, who were acting within the scope of their authority, servitude, workmanship and/or employment described herein, is strictly liable and/or vicariously liable in some or all of the following particulars:

a. That with respect to the Seri Surgical Scaffold Defendant Sofregen misrepresented material facts to the public, including Plaintiff-Wife, St. Clair Hospital and Dr. Pautler, the plastic surgeon, concerning the character, quality and authorized/approved use of the device;

b. That Plaintiff-Wife and Dr. Pautler, the implanting surgeon, justifiably relied on such misrepresentations; and

c. That such justified reliance caused Plaintiff-Wife to suffer physical harm.

34. As a direct and proximate result of the conduct of Defendant Sofregen, as set forth more fully within this Complaint, Plaintiff-Wife sustained the following damages and injuries, some of which may be permanent:

a. Seri Surgical Scaffold removal;

b. Breast implant removal with complete capsulectomy;

c. Infection from complete capsulectomy, which delayed healing process;

d. Breast implant illness;

e. Pain, discomfort and pulling sensation in her chest area;

f. Pain and pulling sensation in her ribs and clavicle;

g. Swollen lymph nodes in her right side;

h. Acne on her neck and face;

i. Hives;

j. Fatigue;

k. Malaise;

l. Severe scarring;

m. Occasional low grade fevers;

n. Traumatic neuroma;

o. Smoldering Myeloma; and

p. Anxiety and depression.

35. As a result of her injuries, Plaintiff-Wife has suffered and will continue to suffer some or all of the following damages:

a. Medical expenses for services and supplies incident to the treatment of her injuries, both past and future;

b. Medical expenses for hospital admissions, surgeries, treatment and therapies, both past and future;

c. Impairment of her general health, strength and vitality;

d. Past and future pain and suffering;

e. Past and future pain, anxiety, mental anguish, embarrassment and inconvenience;

f. Deprivation of her ability to enjoy the normal pleasures of life;

g. Increased complications and corrective procedures;

h. Disfigurement; and

i. Other losses and damages recoverable by law.

WHEREFORE, Plaintiffs, Jennifer Gillespie and Brian Gillespie, demand judgment against Defendant, Sofregen Medical, Inc., in an amount in excess of the compulsory arbitration limits of Allegheny County, Pennsylvania, together with interest and costs of suit.

COUNT II
STRICT LIABILITY
PLAINTIFFS v. ALLERGAN, INC.

36. Plaintiffs incorporate by reference hereto the allegations set forth with paragraphs 1 through 35, inclusive, as though the same were set forth more fully herein at length.

37. At all times relevant hereto, Defendant Allergan designed, developed, tested, assembled, manufactured, packaged, labeled, prepared for distribution, distributed, marketed, supplied and/or sold the Seri Surgical Scaffold either directly and/or indirectly to healthcare providers, hospitals, physicians and medical care recipients, including Plaintiff-Wife.

38. Defendant Allergan, directly and through its officers, directors and its agents, ostensible agents, servants and/or employees, including Defendant Sofregen and Defendant Abbvie, who were acting within the scope of their authority, servitude, workmanship and/or employment described herein, is strictly liable and/or vicariously liable in some or all of the following particulars:

a. The Seri Surgical Scaffold was defective in its design;

b. The Seri Surgical Scaffold was defective in its construction and manufacture;

c. The Seri Surgical Scaffold was not designed or constructed with the proper material or in the proper manner for breast surgery application;

d. The Seri Surgical Scaffold was not accompanied by adequate warnings and instructions in regard to its application in breast reconstruction procedures;

e. In failing to provide healthcare providers, including St. Clair Hospital and Simona Pautler, M.D. with adequate instruction, direction and/or warning regarding the use of the Seri Surgical Scaffold in Plaintiff-Wife's bilateral breast augmentation with bilateral mastopexies surgery;

f. In failing to warn and/or adequately warn physicians and Plaintiff-Wife of any and all dangers and risks involved with the use of the Seri Surgical Scaffold; and

g. In failing to warn and/or adequately warn physicians and Plaintiff-Wife that use of the Seri Surgical Scaffold in breast reconstruction was an unintended and unapproved use of this device.

39. Defendant Allergan, directly and through its officers, directors and its agents, ostensible agents, servants and/or employees, including Defendant Sofregen and Defendant Abbvie, who were acting within the scope of their authority, servitude, workmanship and/or employment described herein, is strictly liable and/or vicariously liable in some or all of the following particulars:

a. That with respect to the Seri Surgical Scaffold Defendant Allergan misrepresented material facts to the public, including Plaintiff-Wife, St. Clair Hospital and Dr. Pautler, the plastic surgeon, concerning the character, quality and authorized/approved use of the device;

b. That Plaintiff-Wife and Dr. Pautler, the implanting surgeon, justifiably relied on such misrepresentations; and

c. That such justified reliance caused Plaintiff-Wife to suffer physical harm.

40. As a direct and proximate result of the conduct of Defendant Allergan, as set forth more fully within this Complaint, Plaintiff-Wife sustained the following damages and injuries, some of which may be permanent:

a. Seri Surgical Scaffold removal;

b. Breast implant removal with complete capsulectomy;

c. Infection from complete capsulectomy, which delayed healing process;

d. Breast implant illness;

e. Pain, discomfort and pulling sensation in her chest area;

f. Pain and pulling sensation in her ribs and clavicle;

g. Swollen lymph nodes in her right side;

h. Acne on her neck and face;

i. Hives;

j. Fatigue;

k. Malaise;

l. Severe scarring;

m. Occasional low grade fevers;

n. Traumatic neuroma;

o. Smoldering Myeloma; and

p. Anxiety and depression.

41. As a result of her injuries, Plaintiff-Wife has suffered and will continue to suffer some or all of the following damages:

a. Medical expenses for services and supplies incident to the treatment of her injuries, both past and future;

b. Medical expenses for hospital admissions, surgeries, treatment and therapies, both past and future;

c. Impairment of her general health, strength and vitality;

d. Past and future pain and suffering;

e. Past and future pain, anxiety, mental anguish, embarrassment and inconvenience;

f. Deprivation of her ability to enjoy the normal pleasures of life;

g. Increased complications and corrective procedures;

h. Disfigurement; and

i. Other losses and damages recoverable by law.

WHEREFORE, Plaintiffs, Jennifer Gillespie and Brian Gillespie, demand judgment against Defendant, Allergan, Inc., in an amount in excess of the compulsory arbitration limits of Allegheny County, Pennsylvania, together with interest and costs of suit.

COUNT III
STRICT LIABILITY
PLAINTIFFS v. ABBVIE, INC.

42. Plaintiffs incorporate by reference hereto the allegations set forth with paragraphs 1 through 41, inclusive, as though the same were set forth more fully herein at length.

43. At all times relevant hereto, Defendant Abbvie designed, developed, tested, assembled, manufactured, packaged, labeled, prepared for distribution, distributed, marketed, supplied and/or sold the Seri Surgical Scaffold either directly and/or indirectly to healthcare providers, hospitals, physicians and medical care recipients, including Plaintiff-Wife.

44. Defendant Abbvie, directly and through its officers, directors and its agents,

ostensible agents, servants and/or employees, including Defendant Sofregen and Defendant Allergan, who were acting within the scope of their authority, servitude, workmanship and/or employment described herein, is strictly liable and/or vicariously liable in some or all of the following particulars:

a. The Seri Surgical Scaffold was defective in its design;

b. The Seri Surgical Scaffold was defective in its construction and manufacture;

c. The Seri Surgical Scaffold was not designed or constructed with the proper material or in the proper manner for breast surgery application;

d. The Seri Surgical Scaffold was not accompanied by adequate warnings and instructions in regard to its application in breast reconstruction procedures;

e. In failing to provide healthcare providers, including St. Clair Hospital and Simona Pautler, M.D. with adequate instruction, direction and/or warning regarding the use of the Seri Surgical Scaffold in Plaintiff-Wife's bilateral breast augmentation with bilateral mastopexies surgery;

f. In failing to warn and/or adequately warn physicians and Plaintiff-Wife of any and all dangers and risks involved with the use of the Seri Surgical Scaffold; and

g. In failing to warn and/or adequately warn physicians and Plaintiff-Wife that use of the Seri Surgical Scaffold in breast reconstruction was an unintended and unapproved use of this device.

45. Defendant Abbvie, directly and through its officers, directors and its agents, ostensible agents, servants and/or employees, including Defendant Sofregen and Defendant Allergan, who were acting within the scope of their authority, servitude, workmanship and/or employment described herein, is strictly liable and/or vicariously liable in some or all of the following particulars:

a. That with respect to the Seri Surgical Scaffold Defendant Abbvie misrepresented material facts to the public, including Plaintiff-Wife, St. Clair Hospital and Dr. Pautler, the plastic surgeon, concerning the character, quality and authorized/approved use of the device;

b. That Plaintiff-Wife and Dr. Pautler, the implanting surgeon, justifiably relied on such misrepresentations; and

c. That such justified reliance caused Plaintiff-Wife to suffer physical harm.

46. As a direct and proximate result of the conduct of Defendant Abbvie, as set forth more fully within this Complaint, Plaintiff-Wife sustained the following damages and injuries, some of which may be permanent:

a. Seri Surgical Scaffold removal;

b. Breast implant removal with complete capsulectomy;

c. Infection from complete capsulectomy, which delayed healing process;

d. Breast implant illness;

e. Pain, discomfort and pulling sensation in her chest area;

f. Pain and pulling sensation in her ribs and clavicle;

g. Swollen lymph nodes in her right side;

h. Acne on her neck and face;

i. Hives;

j. Fatigue;

k. Malaise;

l. Severe scarring;

m. Occasional low grade fevers;

n. Traumatic neuroma;

o. Smoldering Myeloma; and

p. Anxiety and depression.

47. As a result of her injuries, Plaintiff-Wife has suffered and will continue to suffer some or all of the following damages:

a. Medical expenses for services and supplies incident to the treatment of her injuries, both past and future;

b. Medical expenses for hospital admissions, surgeries, treatment and therapies, both past and future;

c. Impairment of her general health, strength and vitality;

d. Past and future pain and suffering;

e. Past and future pain, anxiety, mental anguish, embarrassment and inconvenience;

f. Deprivation of her ability to enjoy the normal pleasures of life;

g. Increased complications and corrective procedures;

h. Disfigurement; and

i. Other losses and damages recoverable by law.

WHEREFORE, Plaintiffs, Jennifer Gillespie and Brian Gillespie, demand judgment against Defendant, Abbvie, Inc., in an amount in excess of the compulsory arbitration limits of Allegheny County, Pennsylvania, together with interest and costs of suit.

COUNT IV
SUCCESSOR LIABILITY
PLAINTIFFS v. ABBVIE, INC.

48. Plaintiffs incorporate by reference hereto paragraphs 1 through 47, inclusive, as if the same were set forth more fully herein at length.

49. It is believed and therefore averred that Defendant Abbvie acquired all of the assets and liabilities of Defendant Allergan in October 2019, including liability for those injuries sustained by Plaintiff-Wife.

50. Alternatively, upon information and belief, the purchase by Defendant Abbvie of the assets and liabilities of Defendant Allergan amounted to a consolidation or merger.

51. Upon information and belief, Defendant Abbvie was merely a continuation of the selling entity, as there was an uninterrupted continuation of business.

52. Upon information and belief, immediately after the consolidation and/or merger, Defendant Allergan ceased being and was replaced by Defendant Abbvie.

53. Upon information and belief, the sale of Defendant Allergan's assets to Defendant Abbvie was entered into without adequate provisions for the protection of creditors of Defendant Allergan.

54. As such, Defendant Abbvie is the successor corporation of Defendant Allergan and is jointly and severally liable to Plaintiffs under a theory of successor liability.

WHEREFORE, Plaintiffs, Jennifer Gillespie and Brian Gillespie, demand judgment against Defendant, Abbvie, Inc., in an amount in excess of the compulsory arbitration limits of Allegheny County, Pennsylvania, together with interest and costs of suit.

COUNT V
NEGLIGENCE
PLAINTIFFS v. SOFREGEN MEDICAL, INC.

55. Plaintiffs incorporate by reference hereto the allegations set forth with paragraphs 1 through 54, inclusive, as though the same were set forth more fully herein at length.

56. At all times relevant hereto, Defendant Sofregen owed a duty to all consumers of its medical devices, including Plaintiff-Wife, to appropriately, sufficiently, satisfactorily and

reasonably design, develop, test, assemble, manufacture, package, label, provide necessary warnings, prepare for distribution, distribute, market, supply and sell the Seri Surgical Scaffold.

57. Defendant Sofregen, directly and through its officers, directors and its agents, ostensible agents, servants and/or employees, including Defendant Allergen and Defendant Abbvie, who were acting within the scope of their authority, servitude, workmanship and/or employment described herein, were negligent and careless in some or all of the following particulars:

a. In negligently designing, manufacturing, assembling, inspecting, testing, approving, distributing, selling, supplying, making available for sale and/or making available for distribution, the Seri Surgical Scaffold as a device to be used for breast reconstruction procedures when it knew or should have known that it was not intended and/or approved for such use;

b. In negligently failing to warn physicians and Plaintiff-Wife of any and all dangers associates with using the Seri Surgical Scaffold in breast reconstruction procedures;

c. In negligently failing to provide healthcare providers, including St. Clair Hospital and Simona Pautler, M.D. with adequate instruction, direction and/or warning regarding the use of the Seri Surgical Scaffold in Plaintiff-Wife's bilateral breast augmentation with bilateral mastopexies surgery;

d. In negligently supplying the Seri Surgical Scaffold to healthcare facilities, doctors and Plaintiff-Wife when it knew or should have known that the device was not approved for use in breast reconstruction procedures;

e. In negligently marketing, distributing, selling and/or supplying the Seri Surgical Scaffold as a device to be used for breast reconstruction procedures when it knew or should have known that it was not cleared and/or approved for such use;

f. In negligently offering for sale the Seri Surgical Scaffold as a device to be used for breast reconstruction procedures when it knew or should have known that it was not intended and/or approved for such use;

h. In continuing to offer for sale the Seri Surgical Scaffold as a device to be used for breast reconstruction procedures when it knew or should have known that it was not intended and/or approved for such use; and

i. In failing to advise Plaintiff-Wife of the May 29, 2015, FDA recall as to allow Plaintiff-Wife to timely discover the unauthorized usage and take appropriate steps to manage and protect her health.

58. As a direct and proximate result of the conduct of Defendant Sofregen, as set forth more fully within this Complaint, Plaintiff-Wife sustained the following damages and injuries, some of which may be permanent:

a. Seri Surgical Scaffold removal;

b. Breast implant removal with complete capsulectomy;

c. Infection from complete capsulectomy, which delayed healing process;

d. Breast implant illness;

e. Pain, discomfort and pulling sensation in her chest area;

f. Pain and pulling sensation in her ribs and clavicle;

g. Swollen lymph nodes in her right side;

h. Acne on her neck and face;

i. Hives;

j. Fatigue;

k. Malaise;

l. Severe scarring;

m. Occasional low grade fevers;

n. Traumatic neuroma;

o. Smoldering Myeloma; and

p. Anxiety and depression.

59. As a result of her injuries, Plaintiff-Wife has suffered and will continue to suffer

some or all of the following damages:

a. Medical expenses for services and supplies incident to the treatment of her injuries, both past and future;

b. Medical expenses for hospital admissions, surgeries, treatment and therapies, both past and future;

c. Impairment of her general health, strength and vitality;

d. Past and future pain and suffering;

e. Past and future pain, anxiety, mental anguish, embarrassment and inconvenience;

f. Deprivation of her ability to enjoy the normal pleasures of life;

g. Increased complications and corrective procedures;

h. Disfigurement; and

i. Other losses and damages recoverable by law.

WHEREFORE, Plaintiffs, Jennifer Gillespie and Brian Gillespie, demand judgment against Defendant, Sofregen Medical, Inc., in an amount in excess of the compulsory arbitration limits of Allegheny County, Pennsylvania, together with interest and costs of suit.

COUNT VI
NEGLIGENCE
PLAINTIFFS v. ALLERGAN, INC.

60. Plaintiffs incorporate by reference hereto the allegations set forth with paragraphs 1 through 59, inclusive, as though the same were set forth more fully herein at length.

61. At all times relevant hereto, Defendant Allergan owed a duty to all consumers of its medical devices, including Plaintiff-Wife, to appropriately, sufficiently, satisfactorily and reasonably design, develop, test, assemble, manufacture, package, label, provide necessary warnings, prepare for distribution, distribute, market, supply and sell the Seri Surgical Scaffold.

62. Defendant Stryker Sales, directly and through its officers, directors and its agents,

ostensible agents, servants and/or employees, including Defendant Sofregen and Defendant Abbvie, who were acting within the scope of their authority, servitude, workmanship and/or employment described herein, were negligent and careless in some or all of the following particulars:

a. In negligently designing, manufacturing, assembling, inspecting, testing, approving, distributing, selling, supplying, making available for sale and/or making available for distribution, the Seri Surgical Scaffold as a device to be used for breast reconstruction procedures when it knew or should have known that it was not intended and/or approved for such use;

b. In negligently failing to warn physicians and Plaintiff-Wife of any and all dangers associates with using the Seri Surgical Scaffold in breast reconstruction procedures;

c. In negligently failing to provide healthcare providers, including St. Clair Hospital and Simona Pautler, M.D. with adequate instruction, direction and/or warning regarding the use of the Seri Surgical Scaffold in Plaintiff-Wife's bilateral breast augmentation with bilateral mastopexies surgery;

d. In negligently supplying the Seri Surgical Scaffold to healthcare facilities, doctors and Plaintiff-Wife when it knew or should have known that the device was not approved for use in breast reconstruction procedures;

e. In negligently marketing, distributing, selling and/or supplying the Seri Surgical Scaffold as a device to be used for breast reconstruction procedures when it knew or should have known that it was not cleared and/or approved for such use;

f. In negligently offering for sale the Seri Surgical Scaffold as a device to be used for breast reconstruction procedures when it knew or should have known that it was not intended and/or approved for such use;

g. In continuing to offer for sale the Seri Surgical Scaffold as a device to be used for breast reconstruction procedures when it knew or should have known that it was not intended and/or approved for such use; and

h. In failing to advise Plaintiff-Wife of the May 29, 2015 FDA recall as to allow Plaintiff-Wife to timely discover the unauthorized usage and take appropriate steps to manage and protect her health.

63. As a direct and proximate result of the conduct of Defendant Allergan, as set forth more fully within this Complaint, Plaintiff-Wife sustained the following damages and injuries, some of which may be permanent:

a. Seri Surgical Scaffold removal;

b. Breast implant removal with complete capsulectomy;

c. Infection from complete capsulectomy, which delayed healing process;

d. Breast implant illness;

e. Pain, discomfort and pulling sensation in her chest area;

f. Pain and pulling sensation in her ribs and clavicle;

g. Swollen lymph nodes in her right side;

h. Acne on her neck and face;

i. Hives;

j. Fatigue;

k. Malaise;

l. Severe scarring;

m. Occasional low grade fevers;

n. Traumatic neuroma;

o. Smoldering Myeloma; and

p. Anxiety and depression.

64. As a result of her injuries, Plaintiff-Wife has suffered and will continue to suffer some or all of the following damages:

a. Medical expenses for services and supplies incident to the treatment of her injuries, both past and future;

b. Medical expenses for hospital admissions, surgeries, treatment and therapies, both past and future;

c. Impairment of her general health, strength and vitality;

d. Past and future pain and suffering;

e. Past and future pain, anxiety, mental anguish, embarrassment and inconvenience;

f. Deprivation of her ability to enjoy the normal pleasures of life;

g. Increased complications and corrective procedures;

h. Disfigurement; and

i. Other losses and damages recoverable by law.

WHEREFORE, Plaintiffs, Jennifer Gillespie and Brian Gillespie, demand judgment against Defendant, Allergan, Inc., in an amount in excess of the compulsory arbitration limits of Allegheny County, Pennsylvania, together with interest and costs of suit.

COUNT VII
NEGLIGENCE
PLAINTIFFS v. ABBVIE, INC.

65. Plaintiffs incorporate by reference hereto the allegations set forth with paragraphs 1 through 64, inclusive, as though the same were set forth more fully herein at length.

66. At all times relevant hereto, Defendant Abbvie owed a duty to all consumers of its medical devices, including Plaintiff-Wife, to appropriately, sufficiently, satisfactorily and reasonably design, develop, test, assemble, manufacture, package, label, provide necessary warnings, prepare for distribution, distribute, market, supply and sell the Seri Surgical Scaffold.

67. Defendant Abbvie, directly and through its officers, directors and its agents, ostensible agents, servants and/or employees, including Defendant Sofregen and Defendant Allergan, who were acting within the scope of their authority, servitude, workmanship and/or

employment described herein, were negligent and careless in some or all of the following particulars:

a. In negligently designing, manufacturing, assembling, inspecting, testing, approving, distributing, selling, supplying, making available for sale and/or making available for distribution, the Seri Surgical Scaffold as a device to be used for breast reconstruction procedures when it knew or should have known that it was not intended and/or approved for such use;

b. In negligently failing to warn physicians and Plaintiff-Wife of any and all dangers associates with using the Seri Surgical Scaffold in breast reconstruction procedures;

c. In negligently failing to provide healthcare providers, including St. Clair Hospital and Simona Pautler, M.D. with adequate instruction, direction and/or warning regarding the use of the Seri Surgical Scaffold in Plaintiff-Wife's bilateral breast augmentation with bilateral mastopexies surgery;

d. In negligently supplying the Seri Surgical Scaffold to healthcare facilities, doctors and Plaintiff-Wife when it knew or should have known that the device was not approved for use in breast reconstruction procedures;

e. In negligently marketing, distributing, selling and/or supplying the Seri Surgical Scaffold as a device to be used for breast reconstruction procedures when it knew or should have known that it was not cleared and/or approved for such use;

f. In negligently offering for sale the Seri Surgical Scaffold as a device to be used for breast reconstruction procedures when it knew or should have known that it was not intended and/or approved for such use;

g. In continuing to offer for sale the Seri Surgical Scaffold as a device to be used for breast reconstruction procedures when it knew or should have known that it was not intended and/or approved for such use; and

h. In failing to advise Plaintiff-Wife of the May 29, 2015 FDA recall as to allow Plaintiff-Wife to timely discover the unauthorized usage and take appropriate steps to manage and protect her health.

68. As a direct and proximate result of the conduct of Defendant Howmedica, as set forth more fully within this Complaint, Plaintiff-Wife sustained the following damages and injuries, some of which may be permanent:

a. Seri Surgical Scaffold removal;

b. Breast implant removal with complete capsulectomy;

c. Infection from complete capsulectomy, which delayed healing process;

d. Breast implant illness;

e. Pain, discomfort and pulling sensation in her chest area;

f. Pain and pulling sensation in her ribs and clavicle;

g. Swollen lymph nodes in her right side;

h. Acne on her neck and face;

i. Hives;

j. Fatigue;

k. Malaise;

l. Severe scarring;

m. Occasional low grade fevers;

n. Traumatic neuroma;

o. Smoldering Myeloma; and

p. Anxiety and depression.

69. As a result of her injuries, Plaintiff-Wife has suffered and will continue to suffer some or all of the following damages:

a. Medical expenses for services and supplies incident to the treatment of her injuries, both past and future;

b. Medical expenses for hospital admissions, surgeries, treatment and therapies, both past and future;

c. Impairment of her general health, strength and vitality;

d. Past and future pain and suffering;

e. Past and future pain, anxiety, mental anguish, embarrassment and inconvenience;

f. Deprivation of her ability to enjoy the normal pleasures of life;

g. Increased complications and corrective procedures;

h. Disfigurement; and

i. Other losses and damages recoverable by law.

WHEREFORE, Plaintiffs, Jennifer Gillespie and Brian Gillespie, demand judgment against Defendant, Abbvie, Inc., in an amount in excess of the compulsory arbitration limits of Allegheny County, Pennsylvania, together with interest and costs of suit.

COUNT IX
LOSS OF CONSORTIUM
PLAINTIFFS v. SOFREGEN MEDICAL, INC.

70. Plaintiffs incorporate by reference hereto the allegations set forth with paragraphs 1 through 69, inclusive, as though the same were set forth more fully herein at length.

71. At all times relevant hereto, Plaintiff-Wife was married to Plaintiff-Husband.

72. As a direct and proximate result of the aforementioned negligent and careless conduct of Defendant Sofregen, as set forth more fully within this Complaint, Plaintiff-Husband has been, and will in the future be, deprived of the society, love, and affection of his wife, all of which have and will in the future continue to cause him great financial damage and loss.

WHEREFORE, Plaintiffs, Jennifer Gillespie and Brian Gillespie, demand judgment against Defendant, Sofregen Medical, Inc., in an amount in excess of the compulsory arbitration limits of Allegheny County, Pennsylvania, together with interest and costs of suit.

COUNT X-LOSS OF CONSORTIUM
PLAINTIFFS v. ALLERGAN, INC.

73. Plaintiffs incorporate by reference hereto the allegations set forth with paragraphs

1 through 72, inclusive, as though the same were set forth more fully herein at length.

74. At all times relevant hereto, Plaintiff-Wife was married to Plaintiff-Husband.

75. As a direct and proximate result of the aforementioned negligent and careless conduct of Defendant Allergan, as set forth more fully within this Complaint, Plaintiff-Husband has been, and will in the future be, deprived of the society, love, and affection of his wife, all of which have and will in the future continue to cause him great financial damage and loss.

WHEREFORE, Plaintiffs, Jennifer Gillespie and Brian Gillespie, demand judgment against Defendant, Allergan, Inc., in an amount in excess of the compulsory arbitration limits of Allegheny County, Pennsylvania, together with interest and costs of suit.

COUNT XI-LOSS OF CONSORTIUM
PLAINTIFFS v. ABBVIE, INC.

76. Plaintiffs incorporate by reference hereto the allegations set forth with paragraphs 1 through 75, inclusive, as though the same were set forth more fully herein at length.

77. At all times relevant hereto, Plaintiff-Wife was married to Plaintiff-Husband.

78. As a direct and proximate result of the aforementioned negligent and careless conduct of Defendant Abbvie, as set forth more fully within this Complaint, Plaintiff-Husband has been, and will in the future be, deprived of the society, love, and affection of his wife, all of which have and will in the future continue to cause him great financial damage and loss.

WHEREFORE, Plaintiffs, Jennifer Gillespie and Brian Gillespie, demand judgment against Defendant, Abbvie, Inc., in an amount in excess of the compulsory arbitration limits of Allegheny County, Pennsylvania, together with interest and costs of suit.

JURY TRIAL DEMANDED

Respectfully submitted,

McKENNA & ASSOCIATES, P.C.

BY: _____

MARK F. McKENNA, ESQUIRE
Attorneys for Plaintiffs, Jennifer Gillespie and Brian Gillespie

VERIFICATION

I am the Plaintiff in this matter and am represented by counsel. I have furnished information upon which the foregoing **Complaint in Civil Action** is based. To the extent that the forgoing is based on the factual information provided to counsel, I verify that those facts are true and correct to the best of my knowledge, information and belief. However, the language is that of counsel and, to the extent that it goes beyond the factual information that I have provided to counsel, I have relied upon counsel in making this verification.

I understand that false statements herein are made subject to the penalties relating to unsworn falsification to authorities.

Date: 2/28/22

Jennifer Gillespie

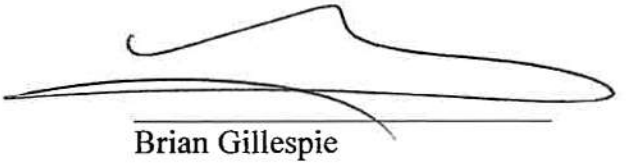
Jennifer Gillespie

VERIFICATION

I am the Plaintiff in this matter and am represented by counsel. I have furnished information upon which the foregoing **Complaint in Civil Action** is based. To the extent that the forgoing is based on the factual information provided to counsel, I verify that those facts are true and correct to the best of my knowledge, information and belief. However, the language is that of counsel and, to the extent that it goes beyond the factual information that I have provided to counsel, I have relied upon counsel in making this verification.

I understand that false statements herein are made subject to the penalties relating to unsworn falsification to authorities.

Date: 4-28-22



Brian Gillespie

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the forgoing Complaint in Civil Action was forwarded via electronic mail and U.S. First Class mail to the following this 2nd day of May 2022:

Andrew F. Susko, Esquire
Joshua E. Gajer, Esquire
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Abbvie, Inc.
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North Chicago, IL 60045

McKENNA & ASSOCIATES, P.C.

BY: _____
MARK F. McKENNA, ESQUIRE
Attorneys for Plaintiffs, Jennifer Gillespie and Brian Gillespie

CERTIFICATE OF COMPLIANCE

I certify that this filing complies with the provisions of the *Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts* that require filing confidential information and documents differently than non-confidential information and documents.

Submitted by: Mark F. McKenna, Esquire

Signature: /s/

Name: Mark F. McKenna

Attorney No. (if applicable): 30297